Remarks

This is in response to the non-final Office Action mailed April 30, 2008. Claims 1-8 and 21-24 remain pending. Reconsideration and allowance are requested for the following reasons.

I. Specification and Claim Amendments

The specification is amended to address informalities. Consideration and entry of the amendments are requested.

Claims 1 and 21 are amended to clarify the claimed subject matter. Claim 2 is amended to address an informality. Consideration and entry are requested.

II. Claim Rejections - 35 U.S.C. § 102

Claims 1 and 4-7 are rejected under 35 U.S.C. § 102(e) as being anticipated by Hunn et al., U.S. Patent Application Publication No. 2004/0158207. This rejection is respectfully traversed, and reconsideration is requested for at least the following reasons.

Claim 1 recites, in part, that the needle is coupled to a housing of the insertion device so that, as the housing is moved relative to the sleeve, the needle is moved relative to the sleeve.

Hunn fails to disclose a housing that is coupled to a needle so that, as the housing is moved relative to a sleeve, the needle is moved relative to the sleeve. Hunn only discloses a needle carrier 27 and needle 8 that are moved within a body 1. See Fig. 9. Hunn lacks both a housing and a sleeve, wherein, as the housing is moved relative to the sleeve, the needle is moved relative to the sleeve.

Claim 1 also recites that manually moving the needle is accomplished without use of an automatic drive mechanism.

Hunn fails to disclose or suggest allowing a patient to <u>manually</u> move the needle of the insertion device from a retracted position to an extended position without use of an automatic drive mechanism. In Hunn, the user presses a button 24 to trigger insertion of the cannula for the Hunn device. The cannula is thereupon automatically inserted by an inserting spring 21. See Hunn, ¶ 0073; Fig. 9. Therefore, Hunn discloses use of an automatic drive mechanism (i.e., the inserting spring 21). Hunn does not disclose manually moving the needle without use of an automatic drive mechanism, as required by claim 1.

Dependent claims 4-7 further define over Hunn. For example, claim 5 recites coupling the set to the site of the infusion device, including positioning the set in an unlocked position over the site, positioning the set onto the site; and moving the set from the unlocked position to a locked position to couple the set to the site and to introduce a needle of the set into a reservoir defined by the site. Further claim 6, which depends from claim 5, recites that the step of moving further comprises sliding a first member of the set relative to a second member of the set to move the set from the unlocked position to the locked position. Hunn fails to disclose or suggest such methods recited in dependent claims 4-7.

Reconsideration and allowance of claim 1, as well as claims 4-7 that depend therefrom, are therefore requested.

III. Claim Rejections - 35 U.S.C. § 103

A. Claims 2 and 3

Claims 2 and 3 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Hunn in view of Mogensen et al., U.S. Patent Application Publication No. 2003/0109829. This rejection is respectfully traversed, and reconsideration is requested for the following reasons.

Claims 2 and 3 depend from claim 1. Mogensen does not remedy the shortcomings of Hunn noted above. For example, Mogensen fails to disclose a housing that is coupled to a need so that, as the housing is moved relative to a sleeve, the needle is moved relative to the sleeve, as required by claim 1. Mogensen also fails to suggest that manually moving the needle is accomplished without use of an automatic drive mechanism, as required by claim 1. Instead, Mogensen discloses an automatic drive mechanism (i.e., drive spring 36) that is used to automatically insert the needle 26. Reconsideration and allowance of claims 2 and 3 are therefore requested.

B. Claim 8

Claim 8 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Hunn in view of Larsen et al., U.S. Patent No. 6,736,797. This rejection is respectfully traversed, and reconsideration is requested for the following reasons.

Claim 8 depends from claim 1. Larsen does not remedy the shortcomings of Hunn noted above. For example, Larsen fails to disclose or suggest a sleeve coupled to a housing the

insertion device that hides the needle prior to retraction, wherein the needle is coupled to the

housing of the insertion device so that, as the housing is moved relative to the sleeve, the needle is moved relative to the sleeve, as recited by claim 1. Instead, Larsen only discloses a separate

insertion needle hub 3 and needle 58, 59 (see Figs. 18 and 26). Reconsideration and allowance

of claim 8 are therefore requested,

C. Claims 21-24

Claims 21-24 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Mogensen

in view of Hunn. This rejection is respectfully traversed, and reconsideration is requested for the

following reasons.

Claim 21 is directed to a method for introducing an infusion device. Claim 21 recites, in

part, that manually moving the needle is accomplished without use of an automatic drive

mechanism.

Claim 21 is therefore allowable over Mogensen and Hunn for at least the same reasons as

those provided above. Reconsideration and allowance of claim 21, as well as claims 22-24 that

depend therefrom, are requested.

IV. Conclusion

Favorable consideration in the form of a Notice of Allowance is requested. Please

contact the undersigned attorney with any questions.

Respectfully submitted,

MERCHANT & GOULD P.C. P.O. Box 2903

Minneapolis, Minnesota 55402-0903

(612) 332-5300

Date: October 29, 2008 /Robert A. Kalinsk

/Robert A. Kalinsky/ Name: Robert A. Kalinsky

Reg. No.: 50,471

9